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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,570	04/30/2001	Seongbong Jo	1789-03805	2225

23505 7590 11/19/2003

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EXAMINER

WAX, ROBERT A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/845,570	Applicant(s) JO ET AL.	
	Examiner Robert A. Wax	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10, 16, 18-20 and 23 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9, 11-15, 17, 21, 22, 24-29 and 32-34 is/are rejected.
- 7) ☒ Claim(s) 7, 30 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>08222001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the peptide RGD in Paper No. 09032002 is acknowledged. Upon reconsideration the restriction is deemed unnecessary and is hereby *withdrawn*.

Priority

2. Applicant has complied with all conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on August 22, 2001 has been considered by the examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 9, 11, 17, 21, 22, 24, 26, 27, 29, 32, 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the term "consisting essentially of" is considered indefinite in this context. In a composition claim the term excludes those ingredients which materially affect the properties of the composition but it is unclear what the term means when applied to a compound (the oligomer).

Claims 9, 17 and 32 are rendered indefinite by the fact that "peptide" is the same as a "protein fragment"; the items in a Markush group must be mutually exclusive.

Claim 11 is essentially a duplicate of claim 9 – it appears that dependency from claim 10 was intended.

Claims 21 and 22 are considered indefinite since they are inconsistent with the teachings of the specification. The specification states that one critical aspect of this invention is the biocompatibility of the polymers and the acrylates are specifically called out as being non-biocompatible. However, these two claims require acrylic groups.

In claim 24 the abbreviation PEG should be spelled out the first time it is used.

Claims 25 and 26 recite inherent properties of the polymers and it is unclear to what extent these claims limit the method of claim 25.

In claim 29 the abbreviation OPF should be spelled out the first time it is used.

Claim 33 is indefinite because there is no antecedent basis for OPF in claim 25.

In claim 34 the abbreviation PPF should be spelled out.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 29 requires activating the OPF however; there is no teaching of how to do so in the specification. Accordingly, it would require undue experimentation for one of ordinary skill in the art to determine how to activate the OPF.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-5, 8, 9, 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rhee et al. 5,874,500.

Rhee et al. teach multi-nucleophilic poly-alkylene oxide crosslinked with multi-electrophilic poly-alkylene oxide. One use is as a drug delivery matrix, biologically active agents are disclosed at column 14, line 66 – column 15, line 37 and include various growth factors and fragments thereof (column 15, line 15). These teachings clearly anticipate the above claims.

10. Claims 24-28 and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Suggs et al. (5,527,864).

Suggs et al. (5,527,864) teach a polymeric network comprising poly (propylene fumarate) copolymerized with poly (ethylene oxide) and crosslinked with an unsaturated linker monomer. These teachings anticipate the above claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-5, 8, 9, 11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee et al. in view of Patel et al.

The teachings of Rhee et al. are outlined above.

Patel et al. teach solid carriers for improved delivery of active ingredients in pharmaceutical compositions comprising polyoxyethylene-polyoxypropylene block copolymers (see column 25, line 60 – column 27, line 33) and various additives. Additives can be, for example, proteins or carbohydrates including cellulose derivatives, starch and chitosan, see column 40, lines 60-63.

It would have been obvious to one of ordinary skill in the art to utilize proteins or carbohydrates as additives to the compositions of Rhee et al. for the advantages taught by Patel et al.

13. Claims 1-5, 8, 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee et al. in view of Hubbell 6,596,267.

The teachings of Rhee et al. are outlined above.

Hubbell et al. teach bioactive species to be used to target adhesion of polyalkylene oxides that include RGD, YIGSR and REDV, see column 6, lines 19-23 and lines 43-60.

It would have been obvious to one of ordinary skill in the art to utilize the bioactive species taught by Hubbell et al. with the polymers of Rhee et al. for the advantages taught by Hubbell et al.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mikos et al. is the patent that issued to the parent application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (703) 308-4471. The examiner can normally be reached on Monday - Friday, 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read "Robert A. Wax". The signature is fluid and cursive, with the first name "Robert" being more prominent than the last name "Wax".

Robert A. Wax
Primary Examiner
Art Unit 1653